UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., and TEVA NEUROSCIENCE, INC., Defendants.	)	Civil Action No. 20-11548

TEVA'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO COMPEL INTERNAL HHS-OIG COMMUNICATIONS

I. Introduction

This Motion pertains to the Government's refusal to produce internal Department of Health and Human Services Office of Inspector General ("HHS-OIG" or "OIG") communications concerning the very agency guidance that the Government seeks to use to support its allegations that Defendants Teva Pharmaceuticals USA, Inc. and Teva Neuroscience, Inc. (collectively, "Teva") violated the Anti-Kickback Statute ("AKS") and the False Claims Act ("FCA"). The Government contends that Teva acted in knowing violation of the guidance, and yet refuses to produce communications reflecting OIG's own interpretations of the guidance. Teva seeks an *in camera* review of the mass redactions applied to the Government's production and an order compelling production.

The Government alleges that Teva violated the AKS and the FCA by making donations to two charitable foundations, the Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"). CDF and TAF provided financial support to multiple sclerosis ("MS") patients who did not have the financial means to pay for their medical treatment which doctors prescribed based upon their clinical judgment.

To prove an AKS violation, the Government must demonstrate that Teva's conduct was knowing and willful. 42 U.S.C. § 1320a-7b(2). To prove an FCA violation, the Government must prove that Teva acted knowingly. 31 U.S.C. § 3729(a)(1). To do so, the Government seeks to rely upon Teva's knowledge of the OIG 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005) (hereinafter, "2005 OIG Guidance"), and HHS-OIG's 2014 Supplemental Advisory Bulletin, Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014) (hereinafter, "2014 OIG Guidance"). Compl., ECF No. 1 at ¶ 67. The Government similarly relies upon HHS-OIG advisory opinions obtained by CDF and TAF to support their claims (the "CDF and TAF Advisory Opinions"), essentially alleging that despite the representations CDF and TAF made to OIG in obtaining the Advisory Opinions, Teva was aware that the charities were not following them. *Id.* ¶¶ 69–70.[1] Teva has pled that its actions were based upon an objectively reasonable interpretation of the 2005 and 2014 OIG Guidance, and that, at best, the Guidance was vague and ambiguous. Answer, ECF No. 39 at 28 ¶ 7.

The interpretation of the 2005 and 2014 OIG Guidance, as well as the CDF and TAF Advisory Opinions, is thus squarely at issue in this litigation. Accordingly, Teva has sought discovery of OIG documents concerning this interpretation. In response to a compromise proposal under which Teva agreed to forgo its requests relating to the Advisory Opinions and focus solely on the Guidance, the Government produced 146 pages of heavily redacted materials, a subsequent privilege log of 212 documents,[2] and has refused to produce more. In other words, the Government's agreement to compromise was a hollow one, as it gave up virtually nothing.

[1] OIG Adv. Op. No. 06-10 (Sept. 14, 2006); (OIG Adv. Op. No. 10-07 (May 26, 2010); Not. of Mod. of OIG Adv. Op. No. 06-10 (Oct. 26, 2015); Nots. of Mod. of OIG Adv. Op. No. 10-07 (May 19, 2011) and (May 5, 2016).
[2] This privilege log included the previously produced heavily redacted documents, as well as additional documents that were withheld entirely. No additional documents were produced.

Furthermore, the Requested Discovery is key to Teva's deposition preparation. For example, on August 24, 2022, Teva served a subpoena noticing its intent to depose HHS-OIG Senior Counsel Heather Westphal. The Government identified Westphal as having primary responsibility for drafting the 2010 Advisory Opinion 10-07 to TAF, including the 2011 and 2016 Modifications, and the 2014 Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs. Westphal is also the custodian of or a correspondent on approximately one third of the documents the Government continues to withhold. Additionally, on an August 10, 2022 meet and confer, the Government took the position that testimony related to certain Rule 30(b)(6) deposition topics[3] Teva noticed would also be protected by the deliberative process privilege, and the Government would object to such testimony. The Government has made it apparent in no uncertain terms that it intends to paint the deliberative process privilege over discovery with as broad a brush as possible, crippling Teva's ability to build its defenses with highly relevant and probative discovery. Teva cannot take meaningful depositions of Westphal or the Government's 30(b)(6) witness without access to the documents and testimony the Government intends to withhold.

Teva thus respectfully seeks an order compelling the Government to produce unredacted versions of the documents, as well as any other documents concerning the interpretation and/or application of the Guidance and Advisory Opinions.

[3] Specifically, Topics 6 ("Your position on whether the 2005 HHS-OIG Guidance was ambiguous, including the extent to which the 2014 HHS-OIG Guidance was promulgated to address, clarify, or rectify any such ambiguity, and the factual basis for Your position."), 7 ("Your position on how a pharmaceutical manufacturer's intent in donating to a single-drug patient assistance program involving that manufacturer's product may be lawful under either the 2005 or 2014 HHS-OIG Guidance, and the factual basis for Your position."), and 8 ("Your position on whether the 2005 HHS-OIG Guidance provided insufficient guidance for pharmaceutical manufacturers regarding permissible conduct as it relates to charitable donations to patient assistance programs, and the factual basis for Your position.").

II. Background

A. HHS-OIG's Special Advisory Bulletins

The Anti-Kickback Statute carries with it potentially broad application and draconian sanctions for those determined to have paid improper inducements. *See Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67 (2d Cir. 2022) ("At least in part because the sanctions under the AKS are severe, Congress created a process by which parties may seek advisory opinions from HHS OIG as to whether a proposed course of action would violate the AKS."). Similarly, the FCA "unquestionably has a punitive aspect." *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 344 (4th Cir. 2022), *reh'g en banc granted*, No. 20-2330, 2022 WL 1467710 (4th Cir. May 10, 2022). The complexity of the fraud and abuse laws, their potentially expansive application, and the significant liability they entail led congress to authorize HHS-OIG to provide "industry guidance, including advisory opinions, safe harbors, and special fraud alerts relating to fraudulent health care practices." Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, § 205, 110 Stat. 1936, 1992 (1996).[4]

This motion pertains to: 1) two Advisory Bulletins issued by OIG pursuant to this authority—the 2005 OIG Guidance and the 2014 OIG Guidance—and the communications concerning them; and 2) OIG Advisory Opinions pertaining to CDF and TAF.

1. The OIG Guidance

a. The 2005 OIG Guidance

On November 22, 2005, in the wake of the implementation of the Medicare Part D prescription drug benefit program, HHS-OIG published the 2005 OIG Guidance, which

[4] OIG recently amended its governing procedures for the issuance of advisory opinions in recognition of the need for "greater transparency regarding factors the Government may consider in evaluating compliance with certain Federal fraud and abuse laws and distinguishing between similar arrangements." 42 C.F.R. 1008 (removing the procedural provision precluding "acceptance of an advisory opinion request and/or issuance of an advisory opinion when the same or substantially the same course of action is under investigation or has been the subject of a proceeding involving HHS or another governmental agency").

acknowledged the long-standing "safety net" that patient assistance programs ("PAPs") provide to "patients of limited means." 70 Fed. Reg. 70623, at 70623. OIG further recognized the "importance of ensuring that financially needy beneficiaries who enroll in [Medicare] Part D receive medically necessary drugs." *Id.* at 70624. Acknowledging the "heightened risks under the [AKS]" of continuing to engage in charitable giving that supports Part D patients, the 2005 OIG Guidance advised that "cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions." *Id.*

OIG stated that it was issuing the Guidance "to identify potentially abusive PAP structures, as well as methods of providing assistance that mitigate or vitiate the potential for fraud and abuse." *Id.* It further stated that "because the Part D benefit has not yet begun, ***and any assessment of fraud and abuse is necessarily speculative***, this Bulletin cannot, and is not intended to, be an exhaustive discussion of relevant risks or beneficial practices." *Id.* (emphasis added). It thereafter set forth five factors that, per OIG, if implemented "should raise few, if any, anti-kickback statute concerns" in the context of donations to independent charitable PAPs. *Id.* at 70626. Those factors are: 1) the pharmaceutical manufacturer and its affiliates do not exert any direct or indirect influence or control over the charity; 2) the charity awards assistance in a truly independent manner that severs the link between the manufactures funding and the beneficiary, providing by way of example that the assistance cannot be attributed to the donating manufacturer; 3) the charity rewards assistance without regard to the manufacturer's interests and without regard to the beneficiary's choice of product, provider, practitioner, supplier, or Part D drug plan; 4) the charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and 5) the manufacturer does not solicit or

receive data from the charity that would facilitate the correlation of the amount of frequency of the manufacturer's donations with the number of subsidized prescriptions for its products. *Id.*

The 2005 OIG Guidance stated that, ultimately, "the independent charity must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices." *Id.* at 70627. Notwithstanding this aim, OIG also recognized that there were circumstances in which "there may only be one drug covered by Part D for the diseases in a particular category or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the diseases in a particular category." *Id.* at 70627 n.16. In other words, OIG did ***not*** prohibit a situation in which a donating manufacturer contributes to a disease state category for which the manufacturer makes the only available treatment, thus 1) acknowledging that, in certain circumstances, a charitable foundation very well may function as a conduit for payments by a pharmaceutical manufacturer to patients on its product, and 2) the correlation OIG identified as posing risk was permissible in some circumstances.

b. The 2014 OIG Guidance

It was not until May 2014, more than eight years after OIG issued the 2005 Guidance, that OIG issued a second Advisory Bulletin addressing independent charity PAPs. *See* 79 Fed. Reg. 31120. The 2014 OIG Guidance acknowledged that it "is based on experience we have gained in the intervening years" since the 2005 OIG Guidance was issued. *Id.* It goes on to describe "additional guidance regarding PAPs operated by independent charities . . . [t]o address some of the specific risks that have come to our attention in recent years[.]" *Id.*

In so doing, OIG referred to previously-issued Advisory Opinions pertaining to the conduct of ***charities***, and stated, for the first time, that the charities' certifications that they would not give a donor information that would enable a donor to correlate the amount of frequency of

its donations with the number of patients using its products were "a material fact" upon which the Advisory Opinions were issued. *Id.* at 31123. Also for the first time, OIG described the charities' procedures of providing only aggregate data to donors as a "critical safeguard." *Id.* The 2014 OIG Guidance further acknowledged that its Advisory Opinions did not pertain to the conduct of donors, and then purported to address that conduct, stating that a donor's correlation of its funding with support for its own products "may be indicative of a donor's intent to channel its financial support to copayments of its own products, which would implicate the anti-kickback statute." *Id.* at 31123.

The Guidance "reiterate[d] . . . that an Independent Charity PAP must not function as a conduit for payments or other benefits from the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries drug choices," *id.* at 31121, but again, nevertheless continued to allow for the existence of a single-drug foundation that would support only that donor's product, thus making clear that a donor's knowledge that donations would benefit patients taking the donor's product is not sufficient to create liability under the AKS, *id.* at 31122.

2. CDF and TAF Advisory Opinions

Consistent with the 2005 OIG Guidance, OIG went on to issue numerous advisory opinions approving independent, bona fide charitable assistance programs that provided financial support to financially needy patients, including programs for Medicare Part D beneficiaries, funded largely by pharmaceutical manufacturers. These included advisory opinions for CDF and TAF. *See* OIG Adv. Op. No. 06-10 (Sept. 14, 2006) (CDF); OIG Adv. Op. No. 10-07 (May 26, 2010) (TAF).[5] These approvals came only after OIG analyzed each charity's certified

[5] Subsequently, OIG modified CDF's advisory opinion (Not. of Mod. of OIG Adv. Op. No. 06-10 (Oct. 26, 2015) and TAF's advisory opinion (Nots. of Mod. of OIG Adv. Op. No. 10-07 (May 19, 2011) and (May 5, 2016)). These modified advisory opinions reflected OIG's continued approval of each charity's patient assistance programs, per the charities' certified information submission.

information against the AKS. OIG Adv. Op. No. 06-10 at 6 (Sept. 14, 2006); OIG Adv. Op. No. 10-07 at 6 (May 26, 2010).

In both advisory opinions, OIG found that the structure of each charity's patient assistance program would interpose an independent, bona fide charitable organization between donors, including pharmaceutical manufactures, in a manner that would insulate beneficiary decision-making from information attributing their funding source to any particular donor. Thus, OIG determined that it was unlikely that donations would influence any beneficiary's selection of a particular provider, practitioner, supplier, test, or product. OIG concluded that "there appears to be a minimal risk that the [donations] would improperly influence referrals by [the charity]." OIG Adv. Op. No. 06-10 at 7 (Sept. 14, 2006); OIG Adv. Op. No. 10-07 at 6 (May 26, 2010).

B. The Government's Claims & Teva's Defenses

On August 18, 2020, the Government filed a complaint against Teva alleging that it violated the FCA for causing the submission of false claims as a result of its donations to CDF and TAF's MS funds. Compl., ECF No. 1 at ¶ 1. The Government alleges that Teva's donations violated the AKS because Teva "intended the payments to ensure that Copaxone patients never faced the steep prices that Teva charges for its drug, thus inducing the patients, including Medicare patients, to purchase the drug." *Id.* at ¶ 2.

To sustain its claims, the Government must prove that Teva acted with the requisite intent. *United States v. Teva Pharms. USA, Inc.*, 560 F. Supp. 3d 412, 419 (D. Mass. 2021); *see also* 42 U.S.C. § 1320a-7b(2). The Government's complaint alleges:

> Teva further knew that federal law did not permit it to cover a Medicare patient's co-pay indirectly by using a foundation as a pass-through vehicle. Lynch and other Teva employees knew that the AKS prohibited Teva from earmarking its money on its drug, Copaxone. ***They were aware of HHS-OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005), and HHS-OIG's 2014***

> ***Supplemental Special Advisory Bulletin, Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120 (May 30, 2014)***.

Compl., ECF No. 1 at ¶ 67 (emphasis added). The Complaint goes on to quote the 2005 and 2014 OIG Guidance, and concludes that, as a result of Teva's knowledge of the Guidance, Teva "knew that the AKS prohibited it from using the foundations as conduits for payments to patients on its drug, and it further knew that HHS-OIG had similarly warned pharmaceutical manufacturers and co-pay foundations." *Id.* at ¶ 68.

Teva has pled that it relied in good faith upon an objectively reasonable interpretation of the 2005 and 2014 OIG Guidance, and the Guidance was, "at best, vague and ambiguous and did not warn Teva away from its interpretation." Answer, ECF No. 39 at 28 ¶ 7.

C. Teva's Discovery Requests

On November 9, 2021, Teva served its First Set of Requests for Production on the Government. RFP Nos. 26, 28, and 29 (the "Requested Discovery" or "internal HHS-OIG communications") sought production of materials related to OIG's drafting, interpretation, application, and enforcement of the 2005 and 2014 OIG Guidance, as well as the CDF and TAF Advisory Opinions. *See* Ex. 2.

The Government initially declined to produce the Requested Discovery on the basis that such documents are not relevant to the Government's claims or Teva's defenses. *See id.*. The Government further maintained that, in the absence of any ambiguity of the AKS or the Guidance, the Government is under no obligation to produce the Requested Discovery under *United States v. Lachman*, 387 F. 3d 42 (1st Cir. 2004) ("*Lachman*") and *United States v. Lachman*, 521 F.3d 12 (1st Cir. 2008) ("*Lachman II*"). Teva disagrees with the Government's interpretation of the *Lachman* cases as described further herein, but nevertheless proposed on April 4, 2022 to limit its requests to all internal HHS-OIG documents (including communications)

relating to or concerning the 2005 or 2014 OIG Guidance that were prepared or created within the twelve (12) months preceding issuance of the applicable document.

In response, the Government offered to produce materials that OIG had provided in response to two 2016 and 2017 Freedom of Information Act ("FOIA") requests for documents reviewed, collected, or prepared in drafting, revising, approving, developing, or implementing the 2005 and 2014 OIG Guidance. Without prejudice to its right or ability to seek the Requested Discovery in full, Teva accepted the Government's offer.

The Government produced the FOIA materials on May 11, 2022. The production was grossly insufficient to satisfy Teva's requests, even under the April 4, 2022 compromise Teva had previously offered. DOJ produced 146 pages of documents, at least 69 pages of which contained heavy redactions or redactions that rendered any understanding of the content of the documents impossible. The vast majority of the unredacted portion of the production consisted of publicly available documents.

Following additional correspondence, the Government agreed to the compromise Teva previously offered on April 4, 2022, and stated it would produce or provide a privilege log for internal HHS-OIG documents relating to or concerning the 2005 HHS-OIG Guidance or the 2014 HHS-OIG Guidance, prepared or created within the twelve (12) months preceding issuance of the applicable document. The Government subsequently served Teva with a privilege log on July 21, 2022. This privilege log listed 212 documents consisting of the previously produced redacted documents and additional documents that had been withheld entirely. The Government asserted that all of the documents were protected by the deliberative process privilege and the attorney-client privilege.[6] The Government produced no additional documents. On July 28,

[6] Except for the Government's initial response to RFP No. 29, the Government had not previously raised the issue of the attorney-client privilege.

2022, Teva responded to the Government that its privilege log did not constitute a sufficient response to Teva's requests, and that the parties were at impasse. Teva reiterated its position that the Government's privilege log was inadequate on an August 2, 2022 meet and confer, and stated that it would be objecting to the Government's privilege assertions. On August 10, 2022, the Government again invoked the deliberative process privilege during a meet and confer regarding certain 30(b)(6) testimony topics, claiming such testimony would be privileged for the same reasons as the Requested Discovery. The Government took a similar position on an August 30, 2022 meet and confer regarding Teva's intended deposition of Westphal.

As further addressed herein, Teva contends that the Requested Discovery is relevant to the Parties' claims and defenses, proportional to the needs of the case, and not barred from disclosure by the privileges the Government asserts.

III. Argument

A. The Federal Rules Permit Broad Discovery Relating to Claims or Defenses

"Under Rule 26, the scope of discovery is broad, and allows a party to 'obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense . . . .'" *KinectUs LLC v. Bumble Trading LLC*, No. 21-91665, 2021 WL 6066539, at *2 (D. Mass. Dec. 22, 2021) (quoting Fed. R. Civ. P. 26(b)(1)); *see also Cumby v. Am. Med. Response, Inc.*, No. 18-30050, 2019 WL 1118103, at *3 (D. Mass. Mar. 11, 2019) ("Fed. R. Civ. P. 26(b)(1)(i) generally permits liberal discovery of relevant information.") (quoting *Baker v. Liggett Grp., Inc.*, 132 F.R.D. 123, 125 (D. Mass. 1990)); Fed. R. Civ. P. 26(b)(1) ("Parties may obtain discovery regarding any matter, not privileged, that is relevant to any party's claim or defense . . . .").

Where the requested discovery relates to a party's specific allegations, as it does here, such information is relevant and discoverable. *HealthEdge Software, Inc. v. Sharp Health Plan*, No. 19-11020, 2021 WL 1821358, at *2 (D. Mass. May 6, 2021). "Once a showing of relevance

is made, the party opposing disclosure bears the burden of showing that the requested discovery is improper." *Controlled Kinematics, Inc. v. Novanta Corp.*, No. 17-11029, 2019 WL 3082354, at *2 (D. Mass. July 15, 2019).

B. Non-Public Agency Statements Are Relevant to Willfulness

Non-public agency statements are relevant to the reasonableness of a defendant's interpretation of a particular regulation, and thus to whether the Government can prove willfulness. *See United States v. Facteau*, No. 15-10076, 2015 WL 6509120 (D. Mass. Oct. 28, 2015). "[N]on-public agency statements might be used to support a good faith defense in cases where there is some evidence that the defendant acted in the good faith belief that his conduct was lawful, and that the agency's internal analysis bolsters the reasonableness of the defendant's interpretation of the law." *Id.* at *4; *see also Lachman II* at 19. Moreover, "[w]here the agency responsible for administration and enforcement of a particular regulation 'issues contradictory or misleading public interpretations of a regulation, there may be sufficient confusion for a regulated party to justifiably claim a deprivation of fair notice.'" *Id.* at *3 (quoting *Lachman*, 1387 F.3d at 57).

This applies to internal HHS-OIG communications. "HHS's internal communications about the decision to issue [guidance] may be relevant to the reasonableness of the Defendants' actions, positions, or interpretations with regard to their determination that the claims at issue were not tainted by an illegal kickback scheme." *United States v. Berkeley Heartlab, Inc.*, No. 11-1593, 2017 WL 2633500, at *6 (D.S.C. June 19, 2017) (citations omitted). Furthermore, "the requested documents may be relevant to defendants' scienter even if defendants were not aware of the content of the Government's internal communications." *Id.* (citation omitted).

The Government has pled that Teva's knowledge of the 2005 and 2014 Guidance demonstrates Teva's knowledge that its conduct was unlawful. Compl., ECF No. 1 at ¶ 67. But, Teva has pled that its actions "were based upon an objectively reasonable interpretation of the

guidelines established by the OIG," and that "[t]he relevant guidelines were, at best, vague and ambiguous and did not warn Teva away from its interpretation." Answer, ECF No. 39 at 28 ¶ 7. The interpretation of the OIG Guidance is thus squarely at issue, and Teva is entitled to discovery of internal OIG documents and communications that may reflect, among other things, both OIG's and the industry's understanding of the Guidance.[7]

C. The Requested Discovery is Proportional to the Needs of the Case

While the Government advanced generalized burden objections in response to Teva's RFPs, at no point in the course of the Parties' meet and confers regarding the RFPs did the Government state that it was withholding the Requested Discovery on the basis of burden. Although the Government stated in its June 10, 2022 letter its position that "the requested documents are not relevant and it would be burdensome to produce them," it immediately followed that it had nonetheless "done a reasonable and diligent search to identify non-privileged materials."[8] June 10, 2022 Letter, Ex. 3. The Government has never articulated to Teva why Rule 26's proportionality factors[9] do not support production of the Requested Discovery, and indeed, application of the factors here favors production.

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[7] The Government's reliance on *Lachman* and *Lachman II* to withhold internal OIG documents is misplaced. Those decisions were within the context of post-trial appeals and where defendants never raised a good faith reliance defense at trial. *Lachman II*, 521 F.3d at 19–20. Moreover, in *Lachman II*, the First Circuit expressly acknowledged that, though defendants were not in possession of the inter-agency materials at the time of their conduct, such materials might support the view that a "reasonable person" might possess such interpretation of the regulation at issue, and "the more reasonable the belief, the more likely it was sincere." *Id.* at 19; *see also United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 348 (4th Cir. 2022) (holding that a defendant cannot be liable under the FCA if he acts consistent with an objectively reasonable interpretation of the law and where the authoritative guidance has not warned defendant away from that interpretation), *reh'g en banc granted*, No. 20-2330, 2022 WL 1467710 (4th Cir. May 10, 2022). That the First Circuit ultimately rejected defendants' arguments on appeal because defendants in *Lachman* never claimed to have held such a belief at trial supports Teva's position that it is entitled to the Requested Discovery in light of its good faith affirmative defense. *Lachman II*, 521 F.3d at 19. Notably, defendants had at the time of trial an affidavit from a former Commerce Department official disputing the definition of the relevant provision advanced by the Government, and yet failed to advance the defense. *Id.*

[8] The Government did not see fit to mention at this time that its completed search had, by the Government's view, identified only privileged materials.

[9] Federal Rule of Civil Procedure 26(b)(1) lists the following considerations for whether discovery is proportional to the needs of the case: "the importance of the issues at stake in the action, the amount in controversy, the parties'

First, the Requested Discovery is directly relevant to and highly probative of Teva's scienter, which is an important issue in the action because it is an essential element that the Government must prove to make its case.

Second, the Government seeks millions of dollars in penalties and damages. *See U.S. ex rel. Long v. Janssen Biotech, Inc.,* No. 16-12182, 2022 WL 488493, at *5 (D. Mass. Feb. 17, 2022) (compelling discovery in AKS-based FCA case where amount in controversy "far exceed[s] one hundred million dollars" even where cost of additional discovery was approximately one million dollars).

Third, the Requested Discovery is uniquely within the possession of the Government. There is no evidence that can substitute the internal HHS-OIG communications, and Teva has no way of accessing the communications without an order from the Court directing their production. *See Diaz v. Devlin,* No. 16-40039, 2018 WL 1610541, at *2 (D. Mass. Apr. 3, 2018) ("The purpose of discovery is to enable the parties 'to obtain the fullest possible knowledge of the issues and facts before trial.'") (quoting *LeBarron v. Haverhill Coop. Sch. Dist.,* 127 F.R.D. 38, 40 (D.N.H. 1989)); *Atchison Casting Corp. v. Marsh, Inc.,* 216 F.R.D. 225, 227 (D. Mass. 2003) ("The broad scope of the discovery rules reflects a policy that '[m]utual knowledge of all the relevant facts gathered by both parties is essential to proper litigation.'") (quoting *Hickman v. Taylor,* 329 U.S. 495, 507 (1947)).

Fourth, the Government purports to have already completed a reasonable and diligent search to identify non-privileged materials responsive to Teva's requests. The Government cannot be said to lack the resources to retrieve the Requested Discovery where it is already in possession of the records and has completed its review.

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relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit."

Fifth, the Requested Discovery is important to resolving the issues because of its probative value regarding Teva's scienter. To the extent the internal HHS-OIG documents shed light on the reasonableness of Teva's interpretation of the 2005 and 2014 Guidance, those documents are of great importance to Teva's defenses. *See Lachman II*, 521 F.3d at 19; *Facteau*, 2015 WL 6509120, at *4; *Berkeley Heartlab, Inc.*, 2017 WL 2633500, at *6.

Sixth, the Government has not articulated any ***specific*** burden, nor can it. The Government claims to have already expended the efforts of collecting and reviewing the communications.[10] All that remains is their unredacted production, a routine litigation effort that presents no unjust burden to the Government.

D. The Deliberative Process Privilege Does Not Bar the Requested Discovery

The Government has asserted the deliberative process privilege over each document on its July 21, 2022 privilege log. 37 of those documents were produced with extensive redactions that make them impossible to understand. For example, the Government produced emails with the entire body of the email text redacted. The remaining 175 documents were withheld entirely. For the reasons that follow, Teva respectfully submits that the deliberative process privilege should not bar production of the Requested Discovery under the circumstances of the instant litigation.

"The deliberative process privilege 'shields from public disclosure confidential inter-agency memoranda on matters of law or policy.'" *Texaco Puerto Rico, Inc. v. Dep't of Consumer Affs.*, 60 F.3d 867, 884 (1st Cir. 1995) (quoting *Nat'l Wildlife Fed'n v. U.S. Forest Serv.*, 861 F.2d 1114, 1116 (9th Cir. 1988)). This privilege is restricted "to materials that are both predecisional and deliberative." *Id.* (citing *EPA v. Mink*, 410 U.S. 73, 88 (1973)). "In other words, to qualify for the privilege, a document must be (1) predecisional, that is, 'antecedent to

[10] However, as described herein in Section E, *infra*, Teva questions the completeness of these efforts.

the adoption of agency policy,' and (2) deliberative, that is, actually 'related to the process by which policies are formulated.'" *Id.* (quoting *Nat'l Wildlife*, 861 F.2d at 1117). "[F]actual statements or post-decisional documents explaining or justifying a decision already made are not shielded." *Id.* at 885 (citations omitted).

"In a discovery dispute, the burden to establish an applicable privilege rests with the party resisting discovery." *F.D.I.C. v. Ogden Corp.*, 202 F.3d 454, 460 (1st Cir. 2000) (citing *United States v. Constr. Prods. Rsch., Inc.*, 73 F.3d 464, 473 (2d Cir. 1996)). Assertion of the deliberative process privilege requires: "(1) a formal claim of privilege by the 'head of the department' having control over the requested information; (2) assertion of the privilege based on actual personal consideration by that official; and (3) a detailed specification of the information for which the privilege is claimed, with an explanation why it properly falls within the scope of the privilege." *Landry v. F.D.I.C.*, 204 F.3d 1125, 1135 (D.C. Cir. 2000) (citations omitted).

Furthermore, the deliberate process privilege is both "qualified" and "discretionary," and "nondisclosure is not automatic" ***even if*** the criteria for the deliberative process privilege is satisfied. *Texaco*, 60 F.3d at 885. A court "determining whether to honor an assertion of the privilege . . . must weigh competing interests" and "should consider, among other things, the interests of the litigants, society's interest in the accuracy and integrity of factfinding, and the public's interest in honest, effective government." *Id.* (citations omitted).[11]

While not exhaustive, the following factors serve as "a floor upon which to balance sufficiently the competing interests of the parties and the federal agency":

> (i) the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the 'seriousness' of the litigation and the issues involved; (iv) the

[11] A major policy expression against a privilege for deliberation was recently stated by Congress in the Government in the Sunshine Act: "It is hereby declared to be the policy of the United States that the public is entitled to the fullest practicable information regarding the decisionmaking processes of the Federal Government." Section 2 of Pub. L. 94-409 Sec. 2, 5 U.S.C. § 552b note (Sept. 13, 1976).

> role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.

In re Pharm. Indus. Average Wholesale Price Litig., 254 F.R.D. 35, 40 (D. Mass. 2008) (citations omitted). "A litigant's showing that the information sought is relevant, helpful, and unavailable from other sources, or essential to a fair determination of a cause, is generally sufficient to overcome the privilege and justify an order of production." *United States ex rel. Drennen v. Fresenius Med. Care Holdings, Inc.*, No. 09-10179, 2019 WL 1254554, at *2 (D. Mass. Mar. 19, 2019) (citing *Ass'n for Reduction of Violence v. Hall*, 734 F.2d 63, 66 (1st Cir. 1984)).

In *United States v. Berkeley Heartlab, Inc.*, No. 11-1593, 2017 WL 3608241, at *2 (D.S.C. Aug. 22, 2017), an AKS-based FCA matter, the court ordered production of Government documents, including internal Government communications about the need for a Special Fraud Alert even though the Government asserted deliberative process privilege because "Defendants' interest in obtaining the [] documents outweighs the Government's need for confidentiality due to the seriousness of this litigation, the Government's role in the litigation, and the potential relevance of these documents to Defendants' argument that they did not have the requisite scienter to be liable for the Government's allegations."

Applied here, balancing of the relevant factors weighs in favor of production. ***First***, the Requested Discovery is directly relevant to the issue of Teva's scienter. The Government has made clear that it intends to rely upon Teva's knowledge of the 2005 and 2014 OIG Guidance to prove that scienter. Compl., ECF No. 1 at ¶ 67. Teva has pled that its actions were based upon an objectively reasonable interpretation of that Guidance, and that, at best, the Guidance was vague and ambiguous. Answer, ECF No. 39 at 28 ¶ 7. Thus, internal HHS-OIG communications interpreting, applying, and discussing the 2005 and 2014 OIG Guidance and the related Advisory Opinions are squarely relevant to Teva's defense, as they may shed invaluable light on OIG's

own opinions regarding the vague and ambiguous nature of the Guidance and its applicability, in turn weighing on the reasonableness and sincerity of Teva's beliefs and interpretations.

Second, there is no alternative evidence that Teva can use in place of these communications to demonstrate OIG's opinions at the time, which are particularly probative.

Third, the issues in this litigation are serious. The Government seeks to use Teva's charitable donations, which helped thousands of patients receive life-sustaining medication they otherwise could not afford, to now assert claims for millions of dollars.

Fourth, the Government is the driving force behind this litigation and occupies a central role. The Requested Discovery is not tangential. The issues in this litigation brought by the Government beg the question of how OIG itself understood the Guidance that the Government now seeks to enforce.

Fifth, production of the documents in this case is unlikely to increase future timidity by Government employees. This is not a FOIA request where the discovery is at risk of being broadly published. Teva seeks only to use the discovery for the limited purpose of defending itself in this litigation. There is a protective order in this case, and the communications at issue can be marked and handled accordingly.

For all these reasons, Teva submits that the internal HHS-OIG communications are "relevant, helpful, and unavailable from other sources," as well as "essential to a fair determination of [Teva's] cause," which "is generally sufficient to overcome the privilege and justify an order of production." *Drennen*, 2019 WL 1254554, at *2 (citing *Hall*, 734 F.2d at 66).

E. Teva Requests *In Camera* Review of the Requested Discovery

When "conducting a balancing test" to determine whether to apply the deliberative process privilege, "a court ***should*** conduct an individualized review of each piece of evidence 'to insure that the balance between [one party's] claims of irrelevance and privilege and [the other's]

asserted need for the documents is correctly struck.'" *In re Pharm. Indus. Average Wholesale Price Litig.*, 254 F.R.D. 35, 40 (D. Mass. 2008) (emphasis added) (quoting *Kerr v. U.S. Dist. Ct. for N. Dist. of Cal.*, 426 U.S. 394, 405 (1976)); *see also Berkeley Heartlab, Inc.*, 2017 WL 2633500, at *6 (ordering the Government to submit responsive documents for *in camera* review "[b]ecause this balancing test ***requires*** a fact-specific inquiry of the documents in question") (emphasis added).

Teva respectfully requests that the Court perform this required *in camera* review as part of its balancing inquiry.

F. Teva Disputes That Every Responsive Document Is Protected by the Attorney-Client Privilege

In addition to the deliberative process privilege, the Government has asserted the attorney-client privilege over every document it identified as responsive to Teva's requests following its initial production of the limited FOIA materials.

The attorney-client privilege only applies:

> (1) Where legal advice of any kind is sought (2) from a professional legal adviser in his capacity as such, (3) the communications relating to that purpose, (4) made in confidence (5) by the client, (6) are at his instance permanently protected (7) from disclosure by himself or by the legal adviser, (8) except the protection be waived.

Neelon v. Krueger, No. 12-11198, 2015 WL 1037992, at *3 (D. Mass. Mar. 10, 2015) (quoting *Comm'r of Revenue v. Comcast Corp.*, 901 N.E.2d 1185, 1194 (Mass. 2009)).

Furthermore, "legal advice is distinguishable from the underlying facts." *ACQIS, LLC v. EMC Corp.,* No. 14-13560, 2017 WL 5709560, at *3 (D. Mass. Nov. 16, 2017) (citing *Upjohn Co. v. United States*, 449 U.S. 383, 395 (1981)). "The distinction between unprotected facts and protected legal advice 'involves considering the source and nature of the information contained in the documents.'" *Id.* (quoting *Lluberes v. Uncommon Prods., LLC*, 663 F.3d 6, 24 (1st Cir. 2011). While communications containing "only client confidences made in pursuit of legal

advice" are protected, "if 'the transmitted information consists largely of facts acquired from non-client sources, those facts are not privileged.'" *Id.* (quoting *Lluberes*, 663 F.3d at 24–25). "Consequently, it does not immunize underlying facts available from another source just because a client disclosed the facts to an attorney." *Americus Mortg. Corp. v. Mark*, No. 12-10158, 2013 WL 5676283, at *4 (D. Mass. Oct. 16, 2013) (citations omitted). As the Supreme Court stated in *Upjohn*, "[t]he privilege only protects disclosure of communications; it does not protect disclosure of the underlying facts by those who communicated with the attorney." 449 U.S. at 395.

Teva does not dispute that there are attorneys included on the communications listed on the Government's July 21, 2022 privilege log. However, after producing the initial FOIA materials, the Government agreed to produce ***all*** internal HHS-OIG documents (including communications) relating to or concerning the 2005 or 2014 OIG Guidance that were prepared or created within the twelve (12) months preceding issuance of the applicable document. Leading up to this agreement, the Government also informed Teva that it had performed a reasonable and diligent search to identify responsive non-privileged materials, and at no point mentioned prior to service of its privilege log that this search was apparently fruitless in its entirety. It is hard to believe that ***every single*** internal HHS-OIG document responsive to the parties' agreed terms involved the provision of legal advice and is protected from disclosure in full. Accordingly, Teva disputes the completeness of the Government's collection and review, as well as its broad application of the privilege over every document identified.[12]

IV. Conclusion

For the foregoing reasons, Teva respectfully requests that this Court grant Teva's motion to compel and order the Government to produce the Requested Discovery.

[12] Teva submits that any *in camera* review of the documents related to the application of the deliberative process privilege could also be used to ensure the propriety of the Government's attorney-client privilege assertions.

Dated: August 30, 2022

Respectfully Submitted,

/s/ Emily Renshaw

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served upon all counsel of record via ECF electronic filing on August 30, 2022.

/s/ Emily Renshaw
Emily Renshaw (BBO #675316)

Dated: August 30, 2022